PATENT

I hereby certify that this correspondence is being electronically filed with the Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 as of the date written immediately below.

Date of Signature

Date of Signature and Deposit: September 20 2007

Attorney of Record

IN THE UNITED STATE PATENT AND TRADEMARK OFFICE

Applicant: Majed M. Hamawy

Serial No.: 10/787,421

Filed: Feb:

February 26, 2004

Title:

MARKER PROTEINS FOR DIAGNOSING SMOOTH MUSCLE CELL

ABNORMALITIES

Art Unit: 1644

Examiner: Nora Maureen Rooney

Commissioner For Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Attn: Mail Stop Non-Fee Amendment

DECLARATION

The undersigned declares that:

- 1. I am the named inventor of the above described patent application.
- 2. I am very familiar with the visualization techniques, and the results thereof, as described in the above application in which homogenates of kidneys from animals were subjected to size cutoff filters, with selected size ranges being subjected to gel electrophoresis followed by immunoblotting with an antiphosphotyrosine antibody.
- 3. I believe that one of ordinary skill in the art, using the description of these techniques contained in the above application, would be able to readily detect, with reasonable specificity, the extent to which the antiphosphotyrosine antibody had bound to an SBP-1/marker

based peptide within the specified size range where the peptide has a phosphorylated tyrosine.

- 4. In this regard, in some of my experiments no peptides having phosphorylated tyrosine showed up in the selected size range (indicating kidney rejection). In others a phosphorylated tyrosine containing peptide based on SBP-1 did show up in the selected size range.
- 5. I am not aware of any experiments of this type where a phosphorylated tyrosine containing peptide from other than the marker protein turned up in the size range in sufficient prominence to cause a false negative problem. Of course, by overexposing beyond normal exposure times one can perceive very minor amounts of background "noise" within the size range. However, this is in such small amounts that even under overexposure conditions that noise has always been readily distinguishable from the prominence of an SBP-1 based peptide within the size range that we regularly see in the case of healthy animal testing.
- 6. In any event, as noted in the above application, and as is evident from our laboratory's article Jose R. Torrealba et al., 5 Amer. Journal of Transplantation 58-67 (2005) (using an antibody to SBP-1 rather than antiphosphotyrosine antibody), I believe that using the teachings of my application, one of ordinary skill in the art could readily develop antibodies having great specificity from the marker proteins I have identified and described the sequence of.

The undersigned declares further that all statements made herein based on personal knowledge of the undersigned are true, that all statements made herein based on information from third parties are believed to be true, and further that all these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under section 1001 of Title 18

U.S.C., and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Majed M. Hamawy

Dated: September 17, 2007

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